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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/393,066	02/23/1995	JOHN H. WOLFE	PENN-0065	1030

7590 07/22/2004

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EXAMINER

CROUCH, DEBORAH

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 07/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/393,066

Applicant(s)

WOLFE ET AL.

Examiner

Deborah Crouch, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1 and 3-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 February 1995 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Applicant's arguments filed April 28, 2004 have been fully considered but they are not persuasive. Claims 1 and 3-9 are pending.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 3-9 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons present in the office action mailed January 28, 2004.

Claims 1 and 3-9 are drawn to a method of stably expressing a selected DNA sequence in the central nervous system of a mammal, comprising administering to peripheral neuron cells of a mammal a neurotropic virus which infects cells of central nervous system of the mammal, the vector containing a selected DNA sequence operatively linked to a LAT so that the selected DNA sequence is stably expressed by infected central nervous system cells for at least four months by the infected central nervous system cells, to a method of stably expressing β -glucuronidase in the brain of a mammal comprising administering to the mammal a neurotropic viral vector which infects cells of the brain of the mammal, said vector being and HSV-1 vector containing a DNA sequence encoding β -glucuronidase operatively linked to a LAT promoter, so that the infected brain cells stably express β -glucuronidase.

While the claimed invention requires only stable expression of the selected DNA sequence, the specification provides no use for mere stable expression. The specification is very clear that the purpose of the delivery method to produce a gene therapy (specification,

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page 2, line 3 to page 3, line 17; page 8, lines 9-13; page 9, line 34 to page 10, line 9; page 16, lines 1-17 and page 20, lines 7-10). Thus, the rejection of the claims as not enabled for gene therapy is clearly appropriate. Applicant is asked to point to page and line number where an alternate use is disclosed.

Applicant argues that the rejection focuses on a reduction to practice, which is not the proper analysis as set forth in MPEP 2164.01. The proper analysis argued by applicant is whether the disclosure contained sufficient information to enable the claimed subject matter. Applicant argues that the presently claimed subject matter relates to methods of stably expressing a selected DNA sequence in the central nervous system of an animal, and not methods of treatment of a disease of the CNS. Applicant argues that the specification discloses how to administer to peripheral neurons, a neurotropic virus vector containing a DNA sequence operatively linked to a selected promoter, as well as other elements of the claims. Applicant argues that the specification teaches at least one use to the skilled artisan, correction of a deficiency in a biological function in cells of the CNS. Applicant argues that just because something hasn't been done is not in itself reason to reject applications disclosing how to do it. Applicant also argues that several neurotropic viruses were known in the art at the time of filing that reach the CNS via peripheral nervous system. These arguments are not persuasive.

Claims are read in light of the specification to guide the skilled artisan on "how to use" the invention. In the present case, the claims are to method of stably expressing a selected DNA sequence in the CNS and brain for at least four months. When the skilled artisan reads the specification for guidance on how to use this method of stable expression, the only disclosed uses are for CNS therapies. In deed, applicant states that they have disclosed at least one use for the claimed subject matter in treating a CNS deficiency. This is a therapeutic method as there is no use in treating a CNS deficiency without allaying a

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symptom associated with the deficiency. Thus, the rejection is a lack of an enabled use for the only disclosed use, a therapeutic treatment. There is no use disclosed for stable expressing without a therapeutic outcome. Applicant's statements regarding the MPEP, a need for a reduction to practice and court decisions would still be persuasive if there were not evidence present in the previous and other office actions that indicates that the claimed subject matter does not meet the requirement for enablement. There aren't any arguments direct towards this aspect of the previous office action. Furthermore, knowledge of promoters or neurotropic viruses is not sufficient to overcome the unpredictability in the claimed methods as a therapy for reasons of record. The art clearly taught at the time of filing that treatment of CNS deficiencies or diseases was unpredictable and with out specific guidance from the specification to achieve CNS therapy by the claimed methods, CNS treatment is not enabled.

The claims are free of the prior art. At the time of filing the cited prior art did not teach or suggest the administration of a viral vector to a peripheral neuron cell with a neurotropic vector comprising a DNA sequence operably linked to a promoter would result in stable expression for at least four months.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant

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to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is 571-272-0727. The examiner can normally be reached on M-Th, 8:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0408. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Deborah Crouch, Ph.D.
Primary Examiner
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July 19, 2004